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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,869	02/12/2002	Chi-Huey Wong	TSRI 696.1	1377

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EXAMINER

WRIGHT, SONYA N

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 12/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/980,869

Applicant(s)

WONG ET AL.

Examiner

Sonya Wright

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 21 and 22 is/are withdrawn from consideration.
- 5) ☒ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-4, and 11-14 is/are rejected.
- 7) ☒ Claim(s) 5-10, 15-20 and 23 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 1-30-02 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 1-23 are pending in this Office Action.

Election/Restrictions

Claims 1-23 are drawn to more than one inventive concept (as defined by PCT Rule 13), and accordingly, a restriction is required according to the provision of PCT Rule 13.2.

PCT Rule 13.2 states that the international application shall related to one invention only or to a group of inventions so linked as to form a single general inventive concept (requirement of unity of invention).

PCT Rule 13.2 states that unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.

Annex B, Part 1(b), provides that "special technical features" mean those technical features which, as a whole, define a contribution over the prior art.

Annex B, Part 1 (e), provides combinations of different categories of claims and states:

"The method for determining unity of invention under Rule 13 shall be construed as permitting, in particular, the inclusion of any one of the following combinations of claims of different categories in the same international application:

(i) in addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for a use of the said product, or

(ii) in addition to an independent claim for a given process, an independent claim for an apparatus or means specifically designed for carrying out the said process, or

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(iii) in addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for an apparatus or means specifically designed for carrying out the said process, . . .”

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-20 and 23, drawn to an inhibitor of hexoaminidase or glycosidase, classified in class 548 and subclass 556.

Group II, claim 21, drawn to an inhibitor of hexoaminidase or glycosidase, classified in class 548 and subclass 518.

Group III, claim 22, drawn to a process for inhibiting a catalytic activity of a hexoaminidase or glycosidase, classified in class 548 and subclasses 518 and 556.

The inventions listed as Groups I, II and III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features that define a contribution over the prior art. The compounds claimed contain a pyrrole ring substituted by hydroxy groups, which does not define a contribution over the art. The compounds of group I differ from the compound of group II because the compounds of group I consist of one pyrrole ring the compound of group two consists of two pyrrole rings. Additionally, groups I and II differ from group III because group III is drawn to a method of use. Accordingly, the

unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper.

During a telephone conversation with Mr. Donald Lewis on December 12, 2002 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-20 and 23. Affirmation of this election must be made by applicant in replying to this Office action. Claims 21 and 22 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 3, and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by STN International ® CAPLUS Database, Accession No. 1997:530913; Wrodnigg et al. Tetrahedron Letters 38 (31), 5463-5466, abstract and US Patent 5,250,703, Fleet et al. Claims 11, 12, 13, and 14, are rejected under 35 U.S.C. 102(b) as being anticipated by Hiranuma et al., "Synthesis and Inhibition Analysis of Five-Membered Homoazasugars

from D-Arabinofuranose via an S_N2 Reaction of the Chloromethylsulfonate”,
Tetrahedron Lett. 36: 8247-8250.

Applicant claims pyrrole compounds which are inhibitors of hexoaminidase or glycosidase. Wrodnigg et al. teach pyrrole compounds which are inhibitors of glucosidase. Fleet et al. teach pyrrole compounds which are inhibitors of glycosidases. Hiranuma et al. teach pyrrole compounds which are inhibitors of glycosidase.

In Wrodnigg et al., see the title for the method of use. Wrodnigg et al. teach a species of the instant compounds, when, in instant claims 1, 2, 3, and 4, R1 is hydrogen, R2 is hydrogen, and R3 is methyl.

In Barta et al., see column 1, lines 9-15 for the method of use. Barta et al. teach a species of the instant claims in column 34, lines 15-25, Example 51. Barta et al. teach a species of the instant compounds, when, in instant claims 1, 2, 3, and 4, R1 is hydrogen, R2 is n-butyl, and R3 is methyl.

In Hiranuma et al., see page 8247, the first sentence, for the method of use as an inhibitor of glycosidases. Hiranuma et al. teach a species of the instant compounds in page 8249, compounds 10a and 10b. Hiranuma et al. teach a species of the instant compounds, when, in instant claims 11, 12, 13, and 14, R1 is hydrogen, R2 is hydrogen, and R3 is a hydroxyl group.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over STN International ® CAPLUS Database, Accession No. 1997:530913; Wrodnigg et al. Tetrahedron Letters 38 (31), 5463-5466, abstract, and US Patent 5,595,981, Barta et al. Claims 11-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hiranuma et al., "Synthesis and Inhibition Analysis of Five-Membered Homoazasugars from D-Arabinofuranose via an S_N2 Reaction of the Chloromethylsulfonate", Tetrahedron Lett. 36: 8247-8250.

Determination of the scope and content of the prior art (MPEP §2141.01)

Applicant claims pyrrole compounds which are inhibitors of hexoaminidase or glycosidase. Wrodnigg et al. teach pyrrole compounds which are inhibitors of glucosidase, an enzyme of glycosidase. Barta et al. teach pyrrole compounds which are inhibitors of glycosidase enzymes. Hiranuma et al. teach pyrrole compounds which are inhibitors of glycosidase.

In Wrodnigg et al., see the title for the method of use. Wrodnigg et al. teach a species of the instant compounds, when, in instant claims 1, 2, 3, and 4, R1 is hydrogen, R2 is hydrogen, and R3 is methyl. Wrodnigg et al. generically teach the instant compounds of claims 1, 2, 3, and 4, when, in instant claims 1, 2, 3, and 4, R1 is hydrogen; R2 is hydrogen, methyl, ethyl, and a branched or unbranched hydrocarbon having between 3 and 8 carbon atoms; and R3 is a hydrocarbon having between 1 and 50 carbon atoms.

In Barta et al., see column 1, lines 9-15 for the method of use. Barta et al. teach a species of the instant claims in column 34, lines 15-25, Example 51. Barta et al. teach

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a species of the instant compounds, when, in instant claims 1, 2, 3, and 4, R1 is hydrogen, R2 is n-butyl, and R3 is methyl. Barta et al. generically teach the instant compounds of claims 1, 2, 3, and 4, when, in instant claims 1, 2, 3, and 4, R1 is hydrogen; R2 is hydrogen, methyl, ethyl, and a branched or unbranched hydrocarbon having between 3 and 8 carbons; and R3 is a hydrocarbon having between 1 and 50 carbon atoms.

In Hiranuma et al., see page 8247, the first sentence, for the method of use as an inhibitor of glycosidases. Hiranuma et al. teach a species of the instant compounds in page 8249, compounds 10a and 10b. Hiranuma et al. teach a species of the instant compounds, in page 8249, compounds 10a and 10b, when, in instant claims 11, 12, 13, and 14, R1 is hydrogen, R2 is hydrogen, and R3 is a hydroxyl group. Hiranuma et al. generically teach the instant compounds of claims 11, 12, 13, and 14, when, in instant claims 11, 12, 13, and 14, R1 is hydrogen; R2 is hydrogen, methyl, ethyl, and a branched or unbranched hydrocarbon having between 3 and 8 carbons; and R3 is hydroxyl.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between Wrodnigg et al. and the instant claims is that in addition to Wrodnigg et al. teaching a species of the instant compounds, Wrodnigg et al. also teach the substitution of hydrogen for methyl (alkyl), and Wrodnigg et al. teach homologs of the methyl group in the –NHAc substituent in the compound of Wrodnigg et al.

The difference between Barta et al. and the instant claims is that in addition to Barta et al. teaching a species of the instant compounds, Barta et al. also teach the

substitution of hydrogen for methyl (alkyl), and Barta et al. teach homologs of the methyl group in the –NHAc substituent in the compound of Barta et al.

The difference between Hiranuma et al. and the instant claims is that in addition to teaching a species of the instant compounds Hiranuma et al. also teach the substitution of hydrogen for methyl.

Finding of prima facie obviousness---rational and motivation (MPEP §2142-2143)

In claims 1, 2, 3, and 4 Applicant defines R2 and R3 to be methyl, ethyl, and a branched or unbranched hydrocarbon having between 3 and 8 carbons while in Wrodnigg et al., the corresponding variables are limited to hydrogen. In Barta et al, there is a generic teaching that hydrogen can be substituted for methyl, see column 2, lines 11 and 12. In claims 11, 12, 13, and 14, Applicant defines R2 to be methyl, ethyl, and a branched or unbranched hydrocarbon having between 3 and 8 carbons, while in Hiranuma et al., the corresponding variables are hydrogens. However, it is well established that the substitution of methyl for hydrogen on a known compound is not a patentable modification absent unexpected or unobvious results. The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (ie., usefulness as an inhibitor of glycosidase).

The instant compounds include alkyl groups of varying lengths (homologs) which are taught by Wrodnigg et al., Barta et al., and Hirnuma et al. To those skilled in chemical art, one homolog is not such an advance over adjacent member of series as requires invention because chemists knowing properties of one member of series would

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in general know what to expect in adjacent members. In re Henze, 85 USPQ 261 (1950). The instant claimed compounds would have been obvious because one skilled in the art would have been motivated to prepare homologs of the compounds taught in the reference with the expectation of obtaining compounds which could be used as inhibitors of glycosidase. Therefore, the instant claimed compounds would have been suggested to one skilled in the art.

Claim Objections

Claim 20 is objected to because of the following informalities: It appears that claim 20 should be dependent on claim 19 instead of claim 9. Claim 20 refers to variable R4, which is found in claim 19, but not in claim 9. Appropriate correction is required.

In claim 23, it appears that "said patient" in the last line should be changed to —said subject— in order to be consistent with two references to a "subject" earlier in the claim.

Claims 5-10, and 15-19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sonya Wright, whose telephone number is (703) 308-4539. The examiner can normally be reached on Monday-Friday from 8:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (703) 308-4537. The Unofficial fax phone number for this Group is (703) 308-7922. The Official fax phone numbers for this Group are (703) 308-4556 or 305-3592.

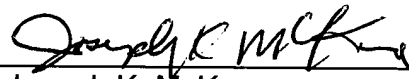
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Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-1235.

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A handwritten signature in black ink, appearing to read "Joseph K. McKane", is written over a horizontal line.

Joseph K. McKane

Supervisory Patent Examiner

Group 1600

Sonya Wright

December 13, 2002